Office Action Summary from USPTO. Acknowledgment was also made of receipt of Applicant's Response to Restriction Requirement filed January 21, 2003 whereby Applicant elected Group 1 with traverse. Claims 19 and 20 (Group 2) were accordingly withdrawn from further Consideration. Claims 1, 11, 12, 17, 18 and 21-23 were rejected by the Examiner in a recent Office Action.

CLAIM REJECTIONS UNDER 35 USC 112

Claims 1, 11, 17 and 18 were rejected under 35 USC 112 as being indefinite. Claim 11, line 1was specifically rejected for containing the indefinite word "including". This term has been replaced by "comprising", a more appropriate and definitive term.

CLAIM REJECTIONS UNDER 35 USC 103(a)

Claims 1, 11, 12, 17, 18 and 21-23 were rejected under 35 USC 103(a) as being unpatentable over Dempski et al. (US 4,900,755, collectively "Dempski") in view of Conte et al. (US 5,738,874, collectively "Conte")

Dempski's discovery of a controlled release form of carbidopa-levodopa was

a major therapeutic advance in the treatment of Parkinson's disease. It stabilized plasma levodopa levels, reduced neurologic and gastrointestinal side effects and increased the duration of antiparkinson activity. However, Dempski's formulation was flawed by a serious 2-hour delay in the onset of action of carbidopa-levodopa. The present invention corrects this flaw via bilayer tablet formulations which provide rapid onset and sustained therapeutic action, a clear clinical advantage for the Parkinson patient in need of expeditious symptomatic control. Moreover, Dempski teaches a single layered tablet, a sustained release profile and excipients which support that profile whereas the present invention teaches a bilayer tablet comprising excipients which support an immediate and sustained release pattern.

Conte's tablet formulations contain immediate and sustained release characteristics, but their arrangement and symmetry, their composition, and their construction are significantly different from those elements of the present invention, as follows:

Three Layer vs Two Layer Tablets. Conte claims a 3-layer tablet consisting of a first layer containing immediate or controlled release

drugs , a second layer containing one or more drugs either equal to or different from the first layer with slow release formulation and a third rate-controlling barrier layer containing drug if necessary. The present invention teaches a 2-layer tablet comprising a sustained release core overcoated only with an immediate release layer.

Multilayer Tablets. In addition to bilayer tablets, the multilayer tablets of the present invention contain an excipient layer which, unlike Conte's third barrier layer, is drug-free and does not contain rate-controlling polymers.

Tablet Construction. Conte claims a tablet consisting of three discrete disc-shaped layers arranged adjacent to one another. Drug release characteristics are a function of exposure of each layer to an aqueous medium and are controlled, in part, by limited aqueous access imposed by the physical structure of the 3-layered tablet. Bilayer tablets of the present invention, on the other hand, consist of a core drug component overcoated by a drug layer which has total external surface exposure and exclusive